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Surveillance of Accredited Laboratories Under Procedures of the National Voluntary Laboratory Accreditation Program (NVLAP)

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U.S. DEPARTMENT OF COMMERCE
NATIONAL BUREAU OF STANDARDS

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SURVEILLANCE OF ACCREDITED LABORATORIES UNDER PROCEDURES OF THE NATIONAL VOLUNTARY LABORATORY ACCREDITATION PROGRAM (NVLAP)

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U.S. DEPARTMENT OF COMMERCE, Clarence J. Brown, *Acting Secretary*
NATIONAL BUREAU OF STANDARDS, Ernest Ambler, *Director*

Surveillance of Accredited Laboratories Under Procedures of the National Voluntary Laboratory Accreditation Program (NVLAP)

by
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The National Bureau of Standards accredits testing laboratories that meet accreditation criteria, for specific test methods or types of tests, developed under the procedures of the National Voluntary Laboratory Accreditation Program (NVLAP). A laboratory which meets the specified NVLAP criteria is deemed to be "competent" to perform the test methods for which it is accredited.

An important issue which must concern all accrediting agencies, including NVLAP, is demonstration of the continued maintenance of a laboratory's competence. Has the laboratory continued to comply with the accreditation criteria a day, week, or six months after the initial determination of competence? The quality and reputation of any laboratory accreditation system relies, in large part, on the measures it takes to assure continuing compliance by a laboratory to all requisite conditions throughout the period of its accreditation.

Since NVLAP is not supported by appropriated funds, it is fully dependent on fees paid by participating laboratories to carry out the functions necessary to confer and continue accreditation. The nature, extent, and frequency of on-site assessments, proficiency testing, and other incurring functions must be balanced against the ability and willingness of laboratories to bear those costs.

There is no practical means for completely assuring day-to-day compliance with accreditation criteria after initial accreditation. NVLAP therefore relies on three mechanisms, described below, to gather information about laboratory performance. They serve as a basis for a reasonable degree of confidence that an accredited laboratory continues to perform at an acceptable level with reference to the NVLAP criteria.

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1. Proficiency testing is a major element of NVLAP's accreditation process. Successful results of proficiency testing are a condition of continuing accreditation in all programs. The requirements of the programs vary, depending on opportunities, costs, difficulty in performing specific tests, availability of test artifacts, cooperation of other organizations (such as standards committees), and other external factors. Several programs call for two "rounds" of testing annually; some are implemented more frequently; others less frequently. The dosimetry program requires proficiency testing prior to initial accreditation and once every two years thereafter, but a testing sequence is performed over a 3-month period.

The results of an individual laboratory's proficiency testing provide an indication of the laboratory's overall ability to carry out a specific test method. If a laboratory's performance is an outlier compared with the group mean, or if it fails to meet a pass/fail criterion, the precise nature of the testing problem cannot be pinpointed. However, unsatisfactory performance clearly indicates that the laboratory is not competent to perform the test method. If the causes of unsatisfactory proficiency testing can be easily determined and are corrected, NVLAP takes no further action with regard to the laboratory's accreditation. Failure to identify the causes, or inability to resolve related problems through discussion between NVLAP and laboratory staff, necessitates special proficiency tests, a special on-site assessment geared particularly to resolving the testing problems, or suspension of the laboratory's accreditation for the pertinent test methods.

2. Regularly scheduled on-site assessments are performed biennially after initial accreditation. NVLAP uses technical experts, as peer assessors, who are very knowledgeable in the applicable fields of testing and have experience in testing and laboratory management. Assessors are assigned so that they do not visit the same laboratory twice in succession. Prior to a laboratory visit, NVLAP provides the assessor with copies of previous assessment reports, applications, proficiency testing results, and any correspondence relevant to the laboratory's testing performance. During regularly scheduled assessments, emphasis is placed on review of areas in which the laboratory had previous deficiencies or difficulties in proficiency testing.

NVLAP also performs monitoring visits on a random or opportunistic basis

(e.g., when travelling for other purposes to a location near an accredited laboratory), or to assure that a laboratory has resolved serious deficiencies or proficiency testing problems.

3. The laboratory's own quality assurance system is a reflection of its commitment to competent testing and good laboratory practices. Conscientious implementation, by the laboratory, of its own QA system is NVLAP's greatest assurance that the laboratory is performing quality testing on a day-to-day basis. NVLAP criteria address quality system requirements in both general and specific terms. NVLAP assessors carefully review quality assurance manuals and related documents; they evaluate management and staff use the manuals and their implementation of the QA system. The absence or inadequacy of quality system documentation constitutes a major deficiency which must be resolved before initial accreditation. Evidence that a laboratory is not fully implementing its own QA system may be grounds for suspension or termination of accreditation.

The community of testing laboratories and their clients is an informal mechanism that assists NVLAP in monitoring continuing compliance of laboratories with the criteria for accreditation. Laboratories inform NVLAP when their competitors make inappropriate claims or act in a manner which might be a violation of NVLAP criteria. These alleged violations most often relate to advertising, use of the NVLAP logo, and issuance of test reports implying product certification or approval. On occasion, test data reported by a NVLAP-accredited laboratory have been challenged by another laboratory. NVLAP has responded by carrying out appropriate reviews by technical experts and conducting investigations necessary to determine if laboratory testing competence was the underlying cause of the complaint.

NVLAP must continually strike a balance between actions to assure continued competence of participating laboratories and the costs of those actions. Participating laboratories must meet the attendant costs of accreditation. The program, therefore, tends to attract laboratories which are committed to maintaining their reputations for high quality testing. Experience has shown that after any significant technical or documentary deficiencies are identified during the initial on-site assessment, and they are resolved, the laboratories maintain an ongoing high level of compliance. Wide discrepancies

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in proficiency testing more often results from limitations in the test methods than from inadequate performance by the laboratories.

With the single exception of the dosimetry program, NVLAP grants accreditation on an annual basis. Yearly reaccreditation contributes significantly to the surveillance process since the submittal of an application by the laboratory affords NVLAP an opportunity to review administrative and technical information provided by the laboratory. Laboratory management attests, by signature, that it continues to be in compliance with the NVLAP accreditation criteria. The annual payment of fees is further affirmation of laboratory management's serious commitment to accreditation.

Laboratories that seek, gain, and maintain NVLAP accreditation highly value that accreditation. They insist that NVLAP conduct its programs to ensure that only highly qualified laboratories obtain accreditation and, with few exceptions, make sincere efforts to comply with the accreditation criteria. That attitude is the most reliable mechanism for assuring continuing competence of accredited laboratories.

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☐ Document describes a computer program; SF-185, FIPS Software Summary, is attached.

11. ABSTRACT (A 200-word or less factual summary of most significant information. If document includes a significant bibliography or literature survey, mention it here)

This paper describes mechanisms by which the National Voluntary Laboratory Accreditation Program (NVLAP) seeks to assure continuing competence of accredited laboratories to perform specific test methods or types of tests. Surveillance of laboratories (defined as actions taken after initial accreditation to ensure continued compliance with accreditation criteria) is achieved through proficiency testing, on-site assessments, and emphasis on the laboratory's own quality assurance system.

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